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Activity of HspE7, a novel immunotherapy, in patients with anogenital warts.

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PURPOSE: Human papillomavirus causes anogenital squamous intraepithelial lesions, warts, and cancer. Treatment of squamous intraepithelial lesions to prevent cancer often requires extensive surgery. We tested a human papillomavirus-specific immunotherapy, HspE7, as a potential alternative. METHODS: HspE7 was constructed by fusing heat shock protein Hsp65 from bacille Calmette-Guerin to E7 protein from human papillomavirus-16. Improvement in pathologic diagnosis of patients with persistent high-grade squamous intraepithelial lesions was studied in an open-label trial (HspE7 500 microg monthly x3). Anogenital warts were not a trial parameter, but a retrospective review of the medical records of the first 22 patients enrolled at one site was undertaken to estimate the quality and frequency of responses of anogenital warts. Patients with warts by physical examination at baseline were scored at 24 weeks as to the percent reduction in wart size. RESULTS: Fourteen of the 22 patients had warts at baseline. At Week 24, 3 of the 14 patients had complete resolution of their warts, and 10 had warts reduced in size an estimated 70 to 95 percent. The remaining patient's warts increased in size. The reduction in size in most patients greatly diminished the procedure necessary for complete ablation. No serious or severe adverse events were related to HspE7. CONCLUSIONS: A retrospective review of patients' medical records suggests that HspE7 may be broadly active in anogenital warts. This activity crosses multiple human papillomavirus types. The warts improved substantially but usually did not totally disappear within six months. Patient follow-up continues. A new randomized, placebo-controlled trial is underway to evaluate these findings.

Publication Types:

- Clinical Trial
- Randomized Controlled Trial

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